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| REED SMITH LLP | | | EXAMINER | |
| 3110 FAIRVIEW PARK DRIVE | | | ARIANI, KADE | |
| FALLS CHURCH, VA 22042 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|------------------------------------|
| Office Action Summary | Application No. 10/563,272 | Applicant(s) BERGE, ROLF |
| | Examiner KADE ARIANI | Art Unit 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 January 2008.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 17 and 21-41 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 17 and 21-41 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1648)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

The amendment filed on 01/04/2008, has been received and entered.

Claims 18-20 have been canceled.

Claims 17 and 21-41 are pending in this application and were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant argues that claims 17-25 were rejected as being indefinite under second paragraph of 35 U.S.C. 112. However:

Claims 17, 21-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention nor was the claimed subject matter described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant alleges that the instant method is a "method of preventing" and as the term "preventing" is an absolute term, the claims cannot be considered enabled for "a method of preventing". To enable "method of preventing" applicant would need to

demonstrate to the skilled artisan that the agent would prevent any and all cases and causes of the claimed disorders and the specification has no such showing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kristisson & Rasco (Critical Reviews in Food Science and Nutrition, 2000, Vol. 40, No.1, p. 43-81).

Claims 17, 21-25 are drawn to a method of treating a disease comprising administering to an animal, a composition comprising an enzyme treated fish protein hydrolysate (FPH) material, wherein the disease is fatty liver, hypercholesterolemia, or hyperhomocysteinemia.

Kristisson & Rasco disclose administering to an animal and human, a composition comprising an enzyme treated fish protein hydrolysate (FPH) material (p.44, 1st column, 2nd paragraph, and p.75 1st column last paragraph).

Applicant's arguments with respect to claims 17, 21-25, filed 1/4/2008 have been fully considered but they are not persuasive.

In response to applicant's argument that Kristisson & Rasco only uses FPH in general food formulations and general antioxidant but not for treating or preventing fatty liver, hypercholesterolemia, and hyperhomocysteinemia, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Kristisson & Rasco do not disclose preventing fatty liver, hypercholesterolemia, and hyperhomocysteinemia, however, the composition being administered is enzyme treated fish protein hydrolysate (FPH) material and therefore has to have the claimed diseases preventing properties.

Therefore, Kristisson & Rasco clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17, and 21-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. (Journal of Nutrition, 1992, vol. 122, p.1731-1737) in view of Kristisson & Rasco (Critical Reviews in Food Science and Nutrition, 2000, Vol. 40, No.1,

p. 43-81) and further in view of Van Guldener & Stehouwer (Expert Opin. Pharmacother. 2001, Vol. 2, No. 9, p.1449-1460).

Claims 17, and 21-41 are drawn to a method of treating or preventing a disease comprising administering to an animal in need of such treatment, a pharmaceutical or nutritional composition comprising an enzyme treated fish protein hydrolysate (FPH) material, wherein the disease is fatty liver, hypercholesterolemia, hyperhomocysteinemia, the animal is human, an agricultural animal, a fish, nutritional composition is a food grade product.

Bergeron et al. teach a method comprising administering to an animal, a nutritional composition comprising fish protein (92.5 % protein). Bergeron et al. teach, "fish protein has been shown to be cholesterol-lowering when fed to rabbits but hypercholesterolemic when included with a 1% corn oil diet, and "current data indicates that fish protein can produce variable effects on serum total cholesterol concentrations, depending in part on the amount and origin of the dietary lipid with which it is combined" (p. 1731 column 1 lines 6-8 and 10-12 and column 2, lines 1-2, also page 1733, Table 1.).

Bergeron et al. teach feeding fish protein to rabbits has consistently been shown to increase HDL cholesterol, compared with casein, and soybean protein, regardless of the fat source and content of the purified diet (p.1731, column 2, lines 9-15).

Bergeron et al. do not teach an enzyme treated fish protein hydrolysate (FPH) material. However, Kristisson & Rasco teach an enzyme treated fish protein hydrolysate material, the use of FPH as a functional food ingredient, and conversion of low value

fish materials into more valuable and palatable products (p. 44, column 1, p. 53-54, p. 74-75).

Applicant's arguments filed 1/4/2008 have been fully considered but they are not persuasive.

Applicant argues that since Kristisson & Rasco does not teach any medical application for FPH, one skilled in the art would not assume Bergeron et al. medical effect of native proteins would be transferable for FPH in Kristisson & Rasco.

However, Kristisson & Rasco teach using FPH for animal feed applications due to its good amino acid balance and high protein content, and antioxidant potential of FPH, and the potential for these products (FPH) to be produced and sold as functional food ingredients (p. 75 1st column last paragraph and 2nd column 1st paragraph, and Conclusion).

Kristisson & Rasco further teach, enzymatic hydrolysis of fish protein has been employed as an alternative approach for converting underutilized fish biomass into edible protein products, using suitable enzyme/substrate ratios and reaction times permits the production of hydrolysate with different molecular structures and different functional properties that could find applications in various food formulations, and to obtain fish protein hydrolysate of a lipid content not exceeding 0.5% by weight as advised by the protein Advisory groups of FAO for a fish protein hydrolysate suitable for human consumption (p. 54 column 1, 2nd paragraph, p. 55 column 1, lines 5-9).

Moreover, at the time the invention was made, it was very well known in the art that, elevation of lipids (cholesterol) in the bloodstream was associated with the development of atherosclerosis and cardiovascular diseases. Also, at the time the

invention was made it was well known that elevated homocysteine levels in blood caused atherosclerotic disease (Van Guldener & Stehouwer, p.1449 -1450).

Therefore, it would have been obvious to one of ordinary skill in the art to use the composition, enzyme treated fish protein hydrolysate, as taught by Kristisson & Rasco in the method of Bergeron et al. to provide a method comprising administering to an animal a composition comprising an enzyme treated fish protein hydrolysate material. The motivation would be to combine the cholesterol lowering effect of fish protein diet as taught by Bergeron et al, with the ability to obtain fish protein hydrolysate with low lipid content, and therefore to lower the risk of cardiovascular diseases.

Claims 26-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielson (US 2002/0182290 A1) and Kristisson & Rasco (Critical Reviews in Food Science and Nutrition, 2000, Vol. 40, No.1, p. 43-81) and further in view of Sharma et al. (Bioresource Technology, 2002, Vol. 85, p.327-329).

Claims 26-41 are drawn to a method of producing an enzyme treated fish protein hydrolysate (FPH), comprising the steps of, hydrolyzing fish flesh remnants with a protease enzyme at a pH in the range of 5.0-8.0 and at a temperature in the range of 40-70°C (in the range of 50-60°C) to yield a hydrolysate, raising the temperature of the solution containing said hydrolysate to the range of 90-99°C, removing an insoluble fraction by decanting and filtering to obtain a remaining mixture, separating the remaining mixture in a three phase separator into an oil fraction, an emulsion fraction, and aqueous fraction, and isolating and filtering the aqueous fraction through an ultra-membrane with a nominal molecular weight limit of 100,000, spray drying the filtered

fraction to obtain the enzyme treated FPH, administering to an animal a pharmaceutical or nutritional composition comprising the enzyme treated FPH, FPH contains 83% protein, fish flesh remnants on salmon bone frames after filleting, a *Bacillus* protease enzyme complex, hydrolysis performed at a pH of 6.5, and the insoluble fraction includes the fish bone frames.

Applicant's arguments filed 1/4/2008 have been fully considered but they are not persuasive,.

Applicant argues that Nielson teaches away from the invention by removing liquid containing soluble protein with oil to obtain clean fish bones rather than removing an insoluble fraction including the fish bone frames from the solution to obtain a remaining mixture in the solution, and Nielsen simply has no teaching included how the hydrolysate is further processed, and what the fish protein hydrolysate might be used for.

Applicant argues that Kristisson & Rasco dislodges the slurry by centrifugation or in some cases filtration, rather than decanting. In addition Kristisson & Rasco directly filters the hydrolysate after enzyme inactivation through membrane rather than decanting.

Applicant argues that the cited references and their combinations fail to teach or suggest each and every feature of the present invention.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Moreover, Nielson teaches a method of producing an enzyme treated fish protein hydrolysate, comprising the steps of, hydrolyzing fish flesh remnants with a protease enzyme at a temperature in the range of 40-70°C to yield a hydrolysate, raising the temperature to about 90-99°C, *Bacillus* protease enzyme complex (Protamax), removing an insoluble fraction by decanting and filtering (the material was sieved), fish flesh remnants on salmon bone frames after filleting, an oil fraction, an emulsion fraction, and aqueous fraction, drying (page 3 and 4, 0037, 0038).

Nielson further teaches a nutritional composition comprising an enzyme treated fish protein hydrolysate material, human, an agricultural animal, fish, and a food grade product (page 3, 0030-0032). Nielson also teaches the protease treatment is conducted at any condition found suitable for the protease and to provide a desired separation of fish meat from the fish bones (page 3, 0029).

Nielson does not teach the claimed amino acid content of the PFH material, proteins in the range 83%, hydrolysis performed at pH 6.5, three-phase separation, an ultra-membrane, and spray drying. However, routine experimentation is widely used by one of ordinary skill in the art to determine optimum or workable ranges of particular parameters such as pH, temperature, concentration of the enzyme or its substrate, and the suitable enzyme in a process. “[W] here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP Chapter 2100 – p.141).

Moreover, Kristisson & Rasco teach, a method of producing an enzyme treated fish protein hydrolysate material, proteins in the range 70-90% (p.57, column 1 lines 21-22), phase separation, ultrafiltration, and spray drying the hydrolysate (p. 63, column 2, lines 1-11, and figure 7 p. 64, column 1 2nd paragraph).

Kristisson & Rasco further teach recovery and alteration of the fish muscle proteins present in the byproduct material and using these as functional ingredients in food systems is a very exciting alternative to discarding (p.43 Introduction 1st).

Furthermore, Sharma et al. teach three-phase partitioning (TPP) has been used for processing proteins and further teaches using TPP process it is possible to simultaneously separate oil and protein (see Abstract and Introduction, and p.328, column 2, 2nd paragraph).

Therefore, it would have been obvious to one of ordinary skill in the art to use three-phase partitioning as taught by Sharma et al. in the method of producing enzyme treated fish protein hydrolysate as taught by Nielson and Kristisson & Rasco, to achieve the predictable result of producing and simultaneously separating fish protein hydrolysate and lipid with a simpler extraction design, also to produce FPH material that can be sold as functional food ingredients.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651

Kade Ariani
Examiner
Art Unit 1651